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EXAMINER	
WAGGLE, JR, LARRY E	
ART UNIT	PAPER NUMBER
3775	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,660	AEBI ET AL.	
	Examiner	Art Unit	
	Larry E. Waggle, Jr	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 June 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11 July 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 12, as shown in Figure 5; 16, as shown in Figure 4; 22, as shown in Figure 5; and 26, as shown in Figure 4. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

On page 2, line 9, the term "verterbral" should read "vertebral."

On page 6, line 3, the term "laprascopic" should read "laparoscopic."

Appropriate correction is required.

Claim Objections

Claim 21 is objected to because of the following informality:

In line 4, the phrase “central axle” should read "central axis” to be consistent with the terminology used in claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "swivel axle" in claims 1-3 and 5-7 is used by the claims to mean "(swivel) axis".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Mitchell (U.S. Patent No. 7,273,496).

Mitchell discloses an intervertebral implant (100) having a central axis, an upper section (110) having a ventral side, a dorsal side, two lateral sides, a top apposition surface (112), and a bottom surface (116) and a lower section (120) having a ventral side, a dorsal side, two lateral sides, a top apposition surface (122), and a bottom surface (126), wherein the two sections (110 and 120) are moveable with respect to each other (column 3, lines 27-30) via two joints arranged between the two sections, the two joints having an upper joint element (150) in the upper section (110), a central joint element (130), and a lower joint element (160) in the lower section (120) (i.e. the first joint is defined by the interaction between 150 (i.e. depression forming the second joint section) and 210 (i.e. first joint section defining a swivel axle with an elevation (i.e. portion extending into 150) having an edge) and the second joint is defined by the interaction between 160 (i.e. depression forming the second joint section) and 220 (i.e. first joint section defining a swivel axle with an elevation (i.e. portion extending into 160) having an edge) (Figures 1-4 and column 3, line 1 – column 7, line 18).

With regard to the statements of intended use and other functional statements, such as "for," they do not impose any structural limitations on the claims distinguishable over the invention of Mitchell which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that

the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell (US Patent 7,273,496).

Mitchell discloses the claimed invention except for the upper / lower joint element comprising an elevation having an edge. It would have been obvious to a person

having ordinary skill in that art at the time of the invention to construct the invention of Mitchell with the upper / lower joint element comprising an elevation having an edge, since it has been held that a mere reversal of the essential working parts of a device (i.e. locating the elevation on the upper / lower joint element as opposed to the first joint section) involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Mitchell discloses the claimed invention except for the swivel axles being warped in relation to each other. It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Mitchell with the swivel axles being warped in relation to each other, since the applicant has not disclosed that such is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a warped swivel axle. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims 8-13 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell (U.S. Patent No. 7,273,496) in view of Krueger et al. (U.S. Publication No. 2004/0143332).

Mitchell discloses the claimed invention except for a means for keeping the ventral side areas at a fixed distance, and means for temporarily blocking mobility, where in the means is an insert with a lower end, an upper end, and a dovetail depression on the ventral sides where the insert can be inserted and the method associated with inserting the implant. Krueger et al. teaches an articulating implant a means (210) for keeping the two sections at a fixed distance and for blocking mobility and can be attached to the ventral side areas of the implant (100). More specifically,

the means has an insert (218) that has an upper surface a lower surface, and the upper and lower sections of the implant (100) have a depression (114) for receiving the implant. The insert can be dovetailed to match the depression (114) (Paragraph 130). Furthermore, the dovetail guides are tapered from the ventral side towards the dorsal side (Figure 42). In use, the insert (218) is inserted into the implant at depression (114), the implant is inserted into the intervertebral space, and the insert (218) is removed after inserting. If further positioning is required, the insert (218) can be reinserted and the implant adjusted (Paragraphs 129-134). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Mitchell with a dovetailed shape insert and a complimentary depression in the plates to block mobility and keep the implant at a fixed height in view of Krueger et al. in order to provide a stabilized insert form implanting into the intervertebral space.

Claims 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell (U.S. Patent No. 7,273,496) in view of Michelson (U.S. Publication No. 2002/0052656).

Mitchell discloses the claimed invention except for the upper and lower sections having two threaded drill holes running through the ventral side to the apposition surfaces with longitudinal axes forming an angle in the range between 20-65 degrees and diverge from the inner surfaces against the apposition surfaces. Michelson teaches an intervertebral implant (800) having upper and lower members. Each member has two threaded holes passing from the interior of implant (800) through the apposition surfaces (Figures 42-46). With further reference to the figures, the holes form angles

with the central axis and diverge from the inner surfaces against the apposition surfaces. The holes are for rigidly securing the implant to the vertebral segment and also to pull each of the adjacent vertebral bodies toward the implant and towards each other (Paragraph 157).

The angle which the longitudinal axes of the holes makes with the central axis is not disclose, It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the holes at an angle between 20 and 65 degrees in relation to the central axis, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Furthermore, the shape of the holes is not disclosed, however, it would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the holes that are conically tapered towards the apposition surfaces, since the applicant has not disclosed that such is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a conically tapered hole. In re Dailey and Eilers, 149 USPQ 47 (1966).

It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Mitchell with two threaded drill holes running through the ventral side to the apposition surfaces with longitudinal axes forming an angle in the range between 20-65 degrees and diverge from the inner surfaces against the apposition surfaces in view of Michelson in order to provide for the implant to be rigidly

secured to the vertebral segments and also so each adjacent vertebrae can be pulled towards each other.

Further, Mitchell discloses the claimed invention except for the central joint section comprising a first catching means and the lower joint section comprising a second catching means engaged with the first catching means. Michelson teach a first joint section (152) comprising a first catching means (156) and a second joint section (154) comprising a second catching means (i.e. the squared off opposing edges of 154) (Figure 1 and paragraph 0126). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Mitchell with the first joint section comprising a first catching means and the second joint section comprising a second catching means in view of Michelson in order to provide a secure releasable connection between the central and lower joint sections.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell (U.S. Patent No. 7,273,496) in view of Hedman et al. (US Patent 4,759,769).

Mitchell discloses the claimed invention except for hinges being attached between the upper joint section and the central joint section through which the two joint sections are held together parallel to the central axis. Hedman et al. teaches two joint sections (42, 54 and 56) being held together (i.e. via 66) by a hinge formation (Figure 1 and column 2, line 44 - column 3, line 34). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Mitchell with the upper and central joint sections being held together by a hinge

formation in view of Hedman et al in order to provide a secure and releasable attachment between the upper and central joint sections.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Pisharodi (US Patent 6,610,093) discloses an intervertebral implant comprising an upper section and a lower section that are moveable in relation to each other via two joints.

Eisermann et al. (US Patent 7,179,294) disclose an intervertebral implant comprising an upper section and a lower section that are moveable in relation to each other via two joints.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry E. Waggle, Jr whose telephone number is (571)270-7110. The examiner can normally be reached on Monday through Thursday, 6:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. E. W./
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775